

The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics Meeting

October 1-3, 2002

Day 1 – October 1, 2002

The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics convened on October 1, 2002, at the Pikesville Hilton in Pikesville, Maryland. The group formed to provide advice and make recommendations to the Secretary of Health and Human Services with respect to the text or content of a proposed rule on coverage requirements for who can bill Medicare for prosthetics and certain custom-fabricated orthotics, pursuant to a Section 427 of the Benefit Improvement Act (BIPA) of 2000. That law states that no Medicare payment “for prosthetics and certain custom-fabricated orthotics shall be made unless furnished by a qualified practitioner and fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate.” The statute directed the Department to use Negotiated Rulemaking. The charge for this Negotiated Rulemaking Committee (Committee) is to reach consensus on the text or content of the proposed rule. To this end, Lynn Sylvester and Ira Lobel of the Federal Mediation and Conciliation Service, an independent agency of the Federal Government, assisted the Committee by facilitating the meeting. This report is a summary of the two and a half-day meeting.

At 9:00 a.m. on October 1, 2002, committee members registration for the Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics began (See Attachment 1-1, Sign-in Sheet). At 10:00 a.m. facilitator Lynn Sylvester started the meeting by welcoming the participants, introducing CMS staff, and reviewing the session agenda (See Attachment 1-2, Agenda). Dr. William Rogers provided an official welcome on behalf of CMS Administrator Scully. He expressed his excitement about using the negotiated rulemaking process, noting that drawing on the expertise of individuals with “real world experience” to fulfill Congress’ direction for payment provisions for custom-fabricated orthotics and prosthetics is an excellent idea. Following Dr. Rogers’ welcome, co-facilitator Ira Lobel had each Committee member introduced themselves and their alternate Committee member and state the reasons they were participating in the negotiated rulemaking. Many of the Committee members stated they wanted to ensure that patients received quality services. Additional themes among the participants’ comments included a desire to ensure patients received competent care by qualified providers; ensuring accessibility to services in rural areas; services provided in a cost effective way; and ensuring that professionals that provide services have credentials to do so. (Written opening statements as provided by members are included with the file copy of the full report as Attachments 1-3 through 1-8.)

Ms. Sylvester provided an overview of the negotiated rulemaking process (See Attachment 1-9, Negotiated Rulemaking) to familiarize the Committee with proceedings that would occur over the course of the meeting. Topics of discussion included: 1) the role of the facilitators, 2) the difference between traditional rulemaking and negotiated rulemaking, 3) the advantages of using the negotiated rulemaking process, 4) key legal requirements, and 5) the importance and meaning of “consensus.”

Prior to dismissing the Committee for a short break, Ms. Sylvester informed the Committee that the Centers for Medicare and Medicaid Services (CMS) would publish a draft regulation using the results of the Negotiated Rulemaking Committee’s work in the Federal Register for public comment once the sessions closed; and minutes of the meeting, excluding attachments, would be posted on a website for access by the Committee and the public.

After the break, the Committee began a discussion on the ground rules for their negotiated rulemaking process. The facilitators distributed sample ground rules from other Negotiated Rulemakings. The facilitators asked the members to indicate their agreement or disagreement by showing a “thumbs up” or “thumbs down” when prompted for a response. One topic that generated significant discussion was whether 100% agreement was needed to reach consensus. The general sentiment was that without 100% support from all the organizations represented, consensus could not be declared. As a result of this conversation, the group unanimously agreed to define “consensus” as the following:

A consensus is a decision which all Committee members or designated alternates present at the meeting can agree upon. The decision may not be everyone’s first choice, but they have heard it and everyone can live with it.

Another topic of major discussion was the expectations of the Committee in regards to what CMS would publish as the Notice of Proposed Rule Making (NPRM) in the Federal Register. After lengthy discussion, the parties agreed to language as follows:

- A. The goal of the Committee is to prepare the basis for a draft Notice of Proposed Rule Making (NPRM). If consensus is not reached on some of the issues presented in the negotiated rulemaking, the Committee shall identify the areas of agreement and disagreement and explanations of any disagreement.*
- B. CMS will circulate a draft NPRM to the Committee for review prior to sending it forward for Departmental clearance. To the extent that the NPRM as published in the Federal Register departs from the consensus report, the parties are free to submit comments regarding the proposed rule.*
- C. If consensus is reached, the Committee will not oppose the same consensus when published in a Notice of Proposed Rulemaking.*

Attachment 1-10, Negotiated Rulemaking Committee Groundrules, is a copy of the complete ground rules as approved by the Committee

The first day closed with a discussion of timeframes for upcoming committee meetings. The group was informed that the next meeting date had already been scheduled for October 29-31, 2002. A number of participants requested the duration of the meetings be held to 2 days. A Committee member from the West Coast also requested, when possible, that meetings be held on Mondays and Tuesdays. The Committee was asked to review their work schedules and be prepared to select future meeting dates prior to returning to their respective cities. The “homework” for the first night was for each member to review the ground rules in preparation for signing-off on the document the following morning.

Finally, the Committee was informed that copies of the meeting minutes would be emailed (to the primary and alternate members), excluding attachments, no later than 7 business days prior to its next meeting, with the first order of business for the next meeting being to review and approve the minutes. The group was instructed to call or email Ms. Sylvester if major issues concerning the minutes were identified.

The group was reminded of the location at time for its reception and the meeting was adjourned for the day.

Day 2 – October 2, 2002

Day two of the Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics meeting began with the group reviewing the edited version of the committee groundrules document, making final edits, and signing-off on the document. (NOTE: The representative of the American Academy of Physical Medicine and Rehabilitation did not sign the agreement at that time but has indicated to the facilitators that he will sign the ground rules at the beginning of the next meeting) Next, the facilitators led a discussion on interest-based negotiations (See Attachment 1-9, Negotiated Rulemaking). A significant portion of this discussion involved the facilitators providing working definitions that would guide the negotiation process.

The facilitators presented seven issues for discussion, based on a convening report, which they shared with the Committee:

1. What and who should be covered by the proposed rule?
2. Interpretation of statutory language “individually fabricated for patient over a positive model of the patient.”
3. How should practitioners be certified, credentialed, or licensed?
4. Who should certify, credential, or license practitioners?
5. How will the program be managed by CMS?
6. Are there special needs, e.g., rural areas?
7. How should the program be implemented?

The entire Committee (primary and alternates) was instructed to self-select a topic of interest for discussion in a small group session. The groups were instructed to generate

sub-issues, where applicable, and define or “flush out” additional questions or areas of concern that need to be addressed/asked when considering the main issue. A representative from each group reported the findings to one of the facilitators, who documented the responses. Typed responses from all the groups were collated and distributed to the Committee. The Committee was asked to review the group responses and 1) identify overlap and duplication (where items can be combined), 2) determine if information provided is within or outside of the scope of the statute (i.e., appropriate for the reg-neg), and 3) prioritize the order of issues to be addressed. Prior to undertaking these instructions, a Committee member suggested the group develop a list of definitions that would allow them to operate using a common understanding of terms. The Committee, in agreement, began to review the group responses and identify words that required a definition. Ms. Sylvester suggested that CMS take the lead on defining the words listed by the Committee by providing definitions developed and recognized by the agency. CMS agreed to provide as many definitions as it could reference and are appropriate to the Committee’s work, not sooner than one week following the adjournment of the first meeting.

Day two of the meeting closed with Committee members revisiting their availability for future meeting dates.

Day 3 – October 3, 2002

The agenda for the third day of the Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics meeting included finalizing the schedule for future meetings, reviewing the edited definitions list and the seven major issues, beginning a discussion on interests relative to the issues, hearing public comments, and determining agenda items for the next meeting.

The Committee agreed to the meeting schedule, as presented below, for upcoming meetings. With the exception of the October 29-31, 2002, meeting, all the meetings will be for two days, starting at 9:00 a.m. and ending at 5:00 p.m.

Meeting Dates:	October 29-31 (Meeting will end at 1:00 p.m. on the third day.)
	December 2-3, 2002 (Depending on facility availability)
	January 6-7, 2003
	February 10-11, 2003
	March 10-11, 2003
	April 7-8, 2003
	May 5-6, 2003 (This is a tentative date.)
	June 2-3, 2003

After scheduling upcoming meeting dates, the group reviewed the edited definitions list and responses to the seven major issues prepared by the facilitators. After noting minor changes, the Committee members were asked to share their respective positions on the issues and explain why the issues were important to the organizations they represented as well as their constituents. Committee responses to the issues, as documented by the

facilitators, are provided as Attachment 1-11, CMS Reg-Neg Definitions and Questions for the Reg-Neg Committee.

When the floor was open for public comment only one individual wished to address the Committee. The individual, speaking on behalf of the Pedorthic Footwear Association (PFA) and certified pedorthists (C.Peds), requested the inclusion of the pedorthic profession as a member to the Negotiated Rulemaking Committee. Among the reasons cited for this request included: 1) C.Peds routinely dispense the L5000, and because it's a prosthetic code, it's in the statute; 2) the Orthotic and Prosthetic (O&P) profession could be negatively impacted if a major portion of the pedorthic practitioners could not survive the decisions made by the Committee; and 3) the belief that any proposed rule involving L-codes will impact pedorthics, especially one involving the issue of qualified providers.

After hearing the public comment, some members of the Committee held a private caucus to discuss the request among themselves and with the PFA representative. During this time they were able to closely review the written request and documentation of comments prepared by the PFA (See Attachments 1-12, Public Comments to the CMS Negotiated Rulemaking Committee; and 1-13, Written Comments on the Proposed Meeting Agenda) despite the statute's explicit exclusion of footwear and shoe inserts. After the caucus, and after further discussions and the caucus report in open session, the members took a vote to see if the group would be added to the committee. Although there were members in favor of including the group, believing they were indeed stakeholders and could inform the discussions, others felt the PFA had a very narrow focus and that current committee members could uphold their interests without formally adding them to the Committee. Members also referenced the statute exclusionary language. The facilitators discouraged the group from postponing a vote until the next meeting. The group briefly considered adding the PFA as a "partial member," i.e., a member without full veto power to halt a consensus. With this suggestion deemed impractical and unfair to the PFA, the group moved to vote on the motion of adding the PFA as a full member of the Negotiated Rulemaking Committee. A consensus could not be reached, and therefore the PFA was not added to the group.

The final task for day three was to develop the agenda for the next committee meeting. The Committee agreed that it would be useful for them to hear presentations from various groups/organizations on the committee to increase their knowledge and subsequently their ability to participate in the negotiation process. Many members also felt that access to all State statutes would be useful. The facilitators asked that a sub-committee be formed to compile useful materials and/or background data that the Committee could use to inform its work by the next meeting. Member John Michael volunteered to head the sub-committee and immediately implement an email group for all members to communicate and contribute to the compilation of materials. CMS also directed the Committee's attention to a number of State statutes provided in the meeting materials.

The agenda for the next meeting, scheduled for October 29-31, 2002, is as follows:

- I. Discussion of definitions and consensus where possible.

- II. Presentations (15-30 minutes) by ABC, BOC, PTs, and OTs, with handouts as applicable.
- III. NCOPE presentation on education program
- IV. Report by sub-committee on data/information the Committee needs (by John Michael)

The meeting adjourned at 1:45 p.m.

List of Attachments

1-1	Sign-in Sheet	Not available electronically.
1-2	Agenda	Not available electronically.
1-3	Opening Statement American Board for Certification in Orthotics and Prosthetics Inc. (notebook included)	Not available electronically.
1-4	Opening Statement National Association for the Advancement of Orthotics and Prosthetics	Not available electronically.
1-5	Opening Statement Board for Orthotist/Prosthetist Certification	Not available electronically.
1-6	Opening Statement American Orthotic and Prosthetic Association	Not available electronically.
1-7	Opening Statement American Academy of Orthotists and Prosthetists	Not available electronically.
1-8	Opening Statement IL and FL Licensure Boards	Not available electronically.
1-9	FMCS Negotiated Rulemaking (packet)	Not available electronically.
1-10	Negotiated Rulemaking Committee Groundrules	Not available electronically.
1-11	CMS Reg-Neg Definitions and Questions for the Reg-Neg Committee	Not available electronically.
1-12	Public Comments to the CMS Negotiated Rulemaking Committee from the Pedorthic Footwear Association (with attachments)	Not available electronically.
1-13	Written Comments on the Proposed Meeting Agenda submitted by the Pedorthic Footwear Association	Not available electronically.
1-14	CMS Handbook of Background Information (Committee Charter, Social Security Act 1861, State Statutes, "L" Codes, Inspector General Report, DMEPOS)	Not available electronically.